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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0316]

Guidance on Inspections of Firms Producing Food Products Susceptible to Contamination With Allergenic Ingredients; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of an inspection guidance entitled "Guidance on Inspections of Firms Producing Food Products Susceptible to Contamination With Allergenic Ingredients." This guidance will assist FDA investigators and inspectors in evaluating conditions that may result in the introduction of undeclared allergens in foods.

DATES: Submit written or electronic comments on this guide at any time.

ADDRESSES: Submit written requests for single copies of the inspection guidance entitled "Guidance on Inspections of Firms Producing Food Products Susceptible to Contamination With Allergenic Ingredients" to the Director, Division of Emergency and Investigational Operations (HFC–130), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–6919. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guide.

Submit written comments concerning the guidance to the Dockets Management Branch (HFS–305), Food and Drug Administration, 5630 Fishers Lane, rm.1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT:

NADI

Technical questions concerning food allergens: Kathy Gombas, Office of Field Programs (HFS–615), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4231, FAX 202–260–0136.

Questions concerning regulatory procedures: Barbara Marcelletti, Office of Regional Operations (HFC–130), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5635, FAX 301–443–6919.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has developed an inspection guidance identifying the following problem areas in the manufacture of foods that may result in undeclared food allergens: (1) Products that contain one or more allergenic ingredients, but the label does not declare the ingredient in the ingredient label; (2) products that become contaminated with an allergenic ingredient due to the firm's failure to exercise adequate control procedures; (3) products that are contaminated with an allergenic ingredient due to the nature of the product or the process; (4) products that contain a flavor ingredient that has an allergenic component, but the label of the product only declares the flavor; and (5) products that contain a processing aid that has an allergenic component, but the label does not declare it. FDA believes there is scientific consensus that the following foods can cause serious allergic reactions in some individuals and account for more than 90 percent of all food allergies: Peanuts, soybeans, milk, eggs, fish, crustacea, tree nuts, and wheat.

FDA is issuing this guidance as level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance is reference material for investigators and other FDA personnel. The guidance does not bind FDA and does not confer any rights, privileges, benefits, or immunities for or on any person(s). An alternative approach may be used if such an approach satisfies the requirements of the applicable statutes, regulations, or both. The guidance will help ensure more effective inspections and further FDA's efforts to prevent potential serious allergic reactions in sensitive individuals resulting from undeclared allergens in food. FDA is

making this guidance document effective immediately because public participation prior to its implementation is not appropriate in these circumstances (21 CFR 10.115). Although the guidance document announced in this notice is being implemented immediately, FDA is requesting comments on the guidance. FDA will review all comments received, revise the guidance in response to the comments as appropriate, and publish a notice of availability if the guidance is revised.

II. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written or electronic comments regarding the guide. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Copies of the guidance may also be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs home page includes the guide and may be accessed at http://www.fda.gov/ora under "Inspectional References."

Dated: 7-27-01

July 27, 2001.

Margaret M. Dotzel,
Associate Commissioner for Policy.

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